



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,992	10/21/2003	Shinn-Zong Lin	60130 (71987)	5673

7590 07/12/2006

Mr. Steven M. Jensen
EDWARDS & ANGELL, LLP
101 Federal Street
Boston, MA 02110

EXAMINER

WINSTON, RANDALL O

ART UNIT	PAPER NUMBER
----------	--------------

1655

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/690,992	Applicant(s) LIN ET AL.	
	Examiner Randall Winston	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 24-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the election of species requirement in its response of 04/27/2006 of isochaihulactone is acknowledged. The traversal is based on the grounds that the elections are made with the understanding that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

Applicant's argument is not found persuasive to traverse the election of species requirement because applicant did not demonstrate that the species are not patentably distinct and applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

The election of species requirement is still deemed proper and is therefore made final.

Claims 19-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Readable claims 1-18 and 24-33 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 and 24-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18 and 24-33 are rendered exceedingly vague and indefinite for reasons to numerous to individually mention.

Claim 1 is rendered vague and indefinite because it is unclear in claim 1 as applicant states in claim 1 that in one instant that you extract a lignan mixture from *Bupleurum scorzonerifolium* meaning you separate the lignan mixture from *Bupleurum scorzonerifolium* than applicant goes back and isolate a pure *Bupleurum scorzonerifolium* extract from the lignan mixture. Thus, what is the lignan mixture comprised of? and after defining and/or clarifying what is the lignan mixture comprised of? what is the pure *Bupleurum scorzonerifolium* extract contained within the lignan mixture?). Clarification is required.

Claim 1 is rendered vague and indefinite because examiner can not delineate the metes and bounds of "lignan mixture" and "pure *Bupleurum scorzonerifolium*" and "isolating". It is unclear to examiner of what are the antineoplastic components of a "lignan mixture"? and what is a "pure *Bupleurum scorzonerifolium*"? and how is the *Bupleurum scorzonerifolium* being isolated from the lignan mixture and how is the *Bupleurum scorzonerifolium* being purified? (i.e. by the chromatographic method?). Clarification is required.

Claim 2 is rendered vague and indefinite because of the term "further comprising of". It is unclear to examiner of how is claim 2 's further comprising language is

incorporated within claim 1 steps. Should the language be "further comprising" language? Clarification is required.

Claim 2 is rendered vague and indefinite because the terms "first extract" "second extract" and "third extract". It is unclear to examiner what are the metes and bounds of the above terms. Is the first extract a lignan mixture comprised of antineoplastic component?, Is the second extract a lignan mixture comprised of an antineoplastic component?, and Is the third extract a lignan mixture comprised of an antineoplastic component? . (It appears within the specification that applicant named the first extract BS-AE, the second extract BS-AE and the third extract BS-HE and then determined each individual extract tumor-suppressing effect). Thus, Is the first extract the same as lignan mixture comprised of antineoplastic component named a pure *Bupleurum scorzonerifolium* extract? The same rationale for the second and third extract also. Clarification is required.

Claim 2 is rendered vague and indefinite because of the term "aqueous portion." It is unclear to examiner what is the metes and bounds of "aqueous portion". Does an "aqueous portion" mean *Bupleurum scorzonerifolium* methanol water extract? Clarification is required.

Claim 5 is rendered vague and indefinite because of the term "95% methanol solution." It is unclear to examiner what is the metes and bounds of "95% methanol solution". Does and "95% methanol solution " comprise of methanol/water and hexane? Clarification is required.

Claim 8 is rendered vague and indefinite because of the phrase "chromatographic method for separating antineoplastic components." It is unclear to examiner when the chromatographic method step is being performed when extracting antineoplastic components from *Bupleurum scorzonerifolium*. It appears to examiner as the phrase reads that chromatographic method is being utilized to separate the antineoplastic components within the lignan mixture. Clarification is required.

Claim 11 is rendered vague and indefinite for the term "pure *Bupleurum scorzonerifolium* extract." The metes and bounds of the above term can not be delineated. What is the pure *Bupleurum scorzonerifolium* extract? Is it first extract or second extract or third extract? Clarification is required.

Claim 12 recites the limitation "the cell proliferative disorder." There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitation "the cell proliferative disorder." There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the cell proliferative disorder." There is insufficient antecedent basis for this limitation in the claim.

Claim 15 recites the limitation "the cell proliferative disorder." There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the cell proliferative disorder." There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the cell proliferative disorder." There is insufficient antecedent basis for this limitation in the claim.

Claim 28 is rendered vague and indefinite for the term "includes." The metes and bounds of the above term can not be delineated. Does applicant means anti-tumor drug is Cisplatin. Clarification is required.

Claim 29 is rendered vague and indefinite for the term "includes." The metes and bounds of the above term can not be delineated. Does applicant means anti-tumor drug is Taxol. Clarification is required.

All other claims depend directly or indirectly from the rejected claims are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Michele C. Flood
MICHELE FLOOD
PRIMARY EXAMINER

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.